REMARKS

Claims 1 and 2 are pending in the application. Claim 1 has been amended herein and claims 3-12 have been canceled. Favorable reconsideration of the application, as amended, is respectfully requested.

I. REJECTION OF CLAIMS 1 AND 2 UNDER 35 U.S.C. § 103(a)

Claims 1 and 2 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kitamura et al. (U.S. Publication No. 2004/0009218) in view of Weissmuller et al. (U.S. Patent No. 6,677,142). The Examiner acknowledges that Kitamura et al. fails to teach the use of an α-1,4-glucan (linear amylose) in tablets, and that neither Kitamura et al. nor Weissmuller et al. teach the use of α-1,4-glucan as a disintegrant. Nevertheless, it is the Examiner's position that it would have been obvious to disclose a disintegrant for tablets consisting of an α-1,4-glucan having a degree of polymerization of not less than 180 and less than 1230 and a dispersity of not more than 1.25, as taught by Kitamura in view of Weissmuller, as the skilled person would have been motivated to make such a product because it has excellent biodegradability, transparency, processability and strength characteristics.

Applicants respectfully traverse the rejection for at least the following reasons. One skilled in the art would not have been motivated to combine the teachings of Kitamura et al. of an enzyme synthesized amylose matrix material with Weissmuller's teaching of a tablet filler with in order to produce disintegrant for a tablet. One skilled in the art would have had no expectation of success that the enzyme synthesized amylose of Kitamura et al. when added to a tablet as in Weissmuller et al. would have provided the specific function of increasing the swellability of the tablet, since the purpose of a filler is contradictory to that of a disintegrant. Applicants have discovered that an α-1,4-glucan having a degree of polymerization of not less than 186 and less than 1230 and a dispersity (weight average molecular weight "Mw"/number average

molecular weight "Mn") of not more than 1.25 unexpectedly provides disintegrating properties when added to a tablet.

Weissmuller discloses that conventional α-1,4-glucan chain containing polysaccharides are useful as tablet fillers. This is based on the concept that conventionally used α-1,4-glucans (for example, starch) have a wide distribution of molecular weights (M_w/M_n is 1.3 or more) and are useful as tablet fillers because they have appropriate properties for tablet fillers. However, α-1,4-glucans having a narrow distribution of molecular weights (M_w/M_n is 1.25 or less) have properties which are significantly different from those of α-1,4-glucans having a wide distribution of molecular weights, and are not suitable as tablet fillers.

Therefore, it would not have been obvious to combine Kitamura with Weissmuller. Specifically, it would not have been obvious to use α-1,4-glucan having a narrow distribution of molecular weights (i.e., M_w/M_n is not more than 1.25) disclosed in Kitamura as the tablet filler as disclosed in Weissmuller, which is based on the concept that the properties of glucans having a wide distribution of molecular weight are function as fillers.

Weissmuller only discloses that α-1,4-glucan chain containing polysaccharides may be used as tablet fillers. As described on page 6, line 26 to page 10, line 4 of the English language specification of the subject application, the properties needed as tablet fillers are quite different from the properties needed as disintegrants for tablets. Fillers have a function of low importance, such as the bulk effect, and very little effect on the properties of a tablet when added. In other words, the matrix material is required not to affect the properties of the tablet and the activity of a drug in the tablet when the matrix material is mixed at any ratio with an active ingredient such as a drug or an additive having another function.

In contrast, a disintegrant is added to a tablet containing an active ingredient for the purpose of achieving quick release of the active ingredient after oral administration. Furthermore, to reduce the size of a tablet or increase the proportion of an active

ingredient in a tablet, there is a need for a binder and a disintegrant which can exert these effects in as small an amount as possible. Usage like this is contradictory to usage as a filler. Accordingly, the use as a disintegrant is quite different from the use as a filler. Thus, those skilled in the art would not have been motivated to use α-1,4-glucans having a narrow distribution of molecular weights in an application as a disintegrant for tablets.

Weissmuller discloses in the Table below columns 7 and 8 various α-1,4-glucan-chain-containing polysaccharides prepared according to the method of Weissmuller. Of all of the polysaccharides of the Table, only those with a M_w less than 200,000 correspond to polysaccharides with a degree of polymerization within the range of 186 to 1230 (e.g., α-1,4-glucans having M_w of 67170, 95670, 101700 or 113300, corresponding to a degree of polymerization of about 414.6, 590.6, 629.8, and 699.4, respectively). However, every one of these polysaccharides has a polydispersity greater than 13. Thus the molecular weights of the α-1,4-glucans disclosed in Weissmuller are widely spread, and would include a large amount of α-1,4-glucans having a degree of polymerization of not less than 1230 and not more than 37000. These particular high molecular weight α-1,4-glucans, when used in a tablet, would act as a binder.

Further, Kitamura one skilled in the art would not expect the amylose disclosed by Kitamura to be superior as a disintegrant for tablets. (See page 6, line 26 to page 10, line 3 of the present specification.) Specifically, Example 4 of Kitamura indicates that a film made from an amylose having Mw of 29.8 kDa (corresponding to a degree of polymerization of 184.0) was brittle. Example 5 of Kitamura indicates that a film made from an amylose having Mw of 110 kDa (corresponding to a degree of polymerization of 679.0) had a high tensile strength. Example 14 of Kitamura indicates that a capsule made from an amylose having Mw of 829 kDa (corresponding to a degree of polymerization of 5117.3) indicates excellent strength. Further, paragraph [0021] of Kitamura describes that the article formed from the enzyme-synthesized amylose is

excellent in strength characteristics. These descriptions indicate that a biodegradable article formed from the enzyme-synthesized amylose described in Kitamura, especially those with high molecular weight, has excellent strength.

Page 214 of "Merriam-Webster's medical desk dictionary" (copy attached in Exhibit A) defines a "diluent" as "a diluting agent (as the vehicle in a medicinal preparation)". This means that the diluent is used for the purpose of bulk effect. Unfortunately, this dictionary does not include the definition of "filler" (copy of page 283 is also attached). However, "filler" is considered to have the same meaning with "diluent" in the field of tablet manufacture.

On the other hand, page 218 of "Merriam-Webster's medical desk dictionary" (copy attached) defines that "disintegrator" is "a substance used in tablet formulations to cause the tablet to break up on contact with moisture and exert its medical action promptly". Disintegrator is considered to have the same meaning with "disintegrant" in the field of tablet manufacture.

As described above and clear from these definitions, in contrast to a filler that is used for the purpose of bulk effect, a disintegrator has to exert a special role of causing disintegration of the tablet. Thus, in view of Kitamura, those skilled in the art would consider that if a tablet is made from an enzyme-synthesized amylose, especially, those having M_w of more than 29.8 kDa, the resultant tablet would have excellent strength, thus, the tablet would not easily disintegrate, and would not be suitable to use as a disintegrant. Thus, those skilled in the art would have no reasonable expectation of success that the amylose of the present invention could be used in a tablet as a disintegrant.

Neither Kitamura nor Weissmuller disclose or suggest that disintegration and bondability are dependent on the degree of polymerization of an α-1,4-glucan. Moreover, neither Kitamura nor Weismuller disclose or suggest that an α-1,4-glucan having a degree of polymerization of not less than 186 and less than 1230, and a polydispersity of not more than 1.25 has a superior property as a disintegrant for tablets.

Because one skilled in the art would have had no reasonable expectation of success, based on the combined teachings of Kitamura and Weismuller that an α-1,4-glucan having a degree of polymerization of not less than 186 and less than 1230 and a dispersity of not more than 1.25 would be a disintegrator in a tablet, prima facie obviousness has not been established. Accordingly, the rejection under 35 U.S.C. §103(a) should be withdrawn.

II. PROVISIONAL DOUBLE PATENTING REJECTION

Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6-12, 18 and 21 of copending Application No. 10/333,267 (Kitamura et al., U.S. Publication No. 2004/0009218) in view of Weissmuller et al. (U.S. 6,677,142). The Examiner contends that claims 1 and 2 of the present application are prima facie obvious over claims 1, 2, 4, 6-12, 18 and 21 of Kitamura et al. in view of Weismuller et al.

Applicants respectfully traverse the rejection. As discussed above, neither Kitamura nor Weismuller disclose or suggest that an α-1,4-glucan having a degree of polymerization of not less than 186 and less than 1230, and a polydispersity of not more than 1.25 has a superior property as a disintegrant for tablets. Because one skilled in the art would have had no reasonable expectation of success, based on the combined teachings of Kitamura and Weismuller that an α-1,4-glucan having a degree of polymerization of not less than 186 and less than 1230 and a dispersity of not more than 1.25 would be a disintegrator in a tablet, prima facie obviousness has not been established. Therefore, the provisional double patenting rejection should be withdrawn.

III. CONCLUSION

Accordingly, claims 1 and 2 are believed to be allowable and the application is believed to be in condition for allowance. A prompt action to such end is earnestly solicited.

Should the Examiner feel that a telephone interview would be helpful to facilitate favorable prosecution of the above-identified application, the Examiner is invited to contact the undersigned at the telephone number provided below.

Should a petition for an extension of time be necessary for the timely reply to the outstanding Office Action (or if such a petition has been made and an additional extension is necessary), petition is hereby made and the Commissioner is authorized to charge any fees (including additional claim fees) to Deposit Account No. 18-0988.

Respectfully submitted,

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